### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **NATIONAL INSTITUTES OF HEALTH**

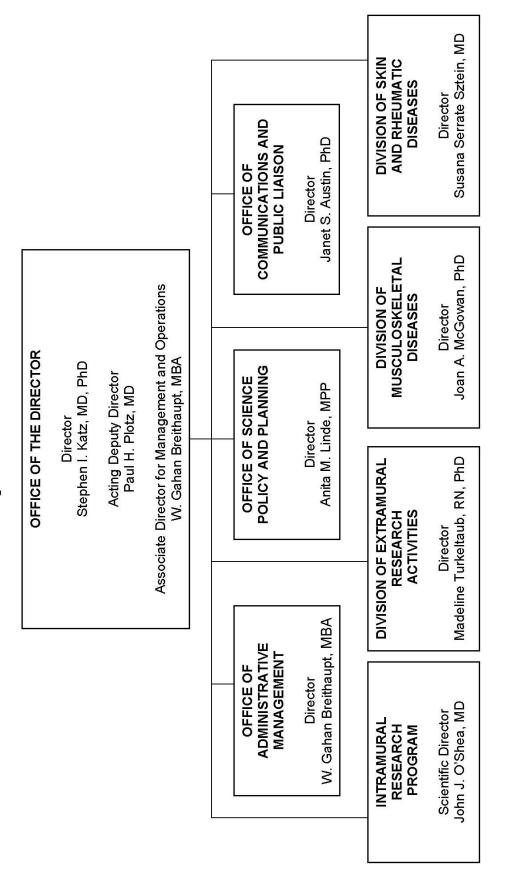
### **National Institute of Arthritis and Musculoskeletal and Skin Diseases**

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## NATIONAL INSTITUTES OF HEALTH

# National Institute of Arthritis and Musculoskeletal and Skin Diseases

### **Organizational Structure**



### NATIONAL INSTITUTES OF HEALTH

### National Institute of Arthritis and Musculoskeletal and Skin Diseases

For carrying out section 301 and title IV of the Public Health Services Act with respect to arthritis and musculoskeletal and skin diseases \$517,629,000, \$509,080,000 (Department of Health and Human Services Appropriation Act, 2008)

### National Institutes of Health National Institute of Arthritis and Musculoskeletal and Skin Diseases

### Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$507,932,000	\$517,629,000	\$509,080,000
Pay cost add-on	308,000	0	0
Rescission	0	-9,043,000	0
Subtotal, adjusted appropriation	508,240,000	508,586,000	509,080,000
Real transfer under Director's one-			
percent transfer authority (GEI)	-866,000	0	0
Comparative transfer to NIBIB	-28,000	0	0
Comparative transfer to OD	-13,000	0	0
Comparative transfer to NCRR	-138,000	0	0
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-1,000	0	0
Comparative transfer under Director's one-percent transfer authority (GEI)	866,000	0	0
Subtotal, adjusted budget authority	508,060,000	508,586,000	509,080,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	508,060,000	508,586,000	509,080,000
Unobligated balance lapsing	-82,000	0	0
Total obligations	507,978,000	508,586,000	509,080,000

<sup>1/</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2007 - \$747,000 FY 2008 - \$1,000,000 FY 2009 - \$1,000,000. Excludes \$150,000 in FY 2008 and \$150,000 in FY 2009 for royalties.

### **NATIONAL INSTITUTES OF HEALTH**

### National Institute of Arthritis and Musculoskeletal and Skin Diseases

(Dollars in Thousands)

Budget Mechanism - Total

		2007		2008		2009		
MECHANISM		ctual		nacted		timate		hange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								_
Noncompeting	751	\$245,802	762	\$247,780	766	\$244,853	4	-\$2,927
Administrative supplements	(26)	1,231	(27)	1,245	(27)	1,245	(0)	0
Competing:							_	
Renewal	61	24,382	57	22,833	59	23,530	2	697
New	199	51,494	184	48,222	189	49,693	5	1,471
Supplements	1	78	1	75	1	75	0	0
Subtotal, competing	261	75,954	242	71,130	249	73,298	7	2,168
Subtotal, RPGs	1,012	322,987	1,004	320,155	1,015	319,396	11	-759
SBIR/STTR	40	12,067	40	11,979	40	11,950	0	-29
Subtotal, RPGs	1,052	335,054	1,044	332,134	1,055	331,346	11	-788
Research Centers:								
Specialized/comprehensive	38	40,684	38	40,684	38	40,684	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	38	40,684	38	40,684	38	40,684	0	0
Other Research:								
Research careers	149	17,760	154	18,315	154	18,315	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	22	2,684	22	3,960	22	3,960	0	0
Subtotal, Other Research	171	20,444	176	22,275	176	22,275	0	0
Total Research Grants	1,261	396,182	1,258	395,093	1,269	394,305	11	-788
Research Training:	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>			
Individual awards	57	2,630	57	2,630	57	2,654	0	24
Institutional awards	262	12,816	262	12,816	262	12,931	0	115
Total, Training	319	15,446	319	15,446	319	15,585	0	139
Research & development contracts	57	21,612	57	21,850	57	21,850	0	0
(SBIR/STTR)	(0)	(29)	(0)	(29)	(0)	(29)	(0)	(0)
, ,	FTEs	` '	<u>FTEs</u>	, ,	FTEs	` '	FTEs	
Intramural research	131	50,834	133	51,851	134	52,629	1	778
Research management and support	84	23,986	84	24,346	85	24,711	1	365
	04		04		65		1	
Construction		0		0		0		0
Buildings and Facilities	245		047	-	24.0	-	^	0
Total, NIAMS	215	508,060	217	508,586	219	509,080	2	494

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

## NATIONAL INSTITUTES OF HEALTH National Institute of Arthritis and Musculoskeletal and Skin Diseases BA by Program (Dollars in thousands)

	C007 L	Ε¥Σ	FY 2006	FY 2	FY 2007	F	FY 2007	Ŧ	FY 2008	F	FY 2009		
	tual	Act	Actual	Actual	nal	Comp	Comparable	Ena	Enacted	Esti	Estimate	Change	Je.
IIIIai Researcii	FTEs Amount F	FTEs Amount	SHOOL SHOOL	FTEs Amount		FTES .	TEs Amount	FTEs Amount	Amount	FTES	FTEs Amount	FTEs Amount	ount
<u>Detail:</u>													
Arthritis and Rheumatic Diseases \$13	\$139,763	↔	\$139,329	\$	\$135,318		\$135,572		\$135,305		\$135,103	•	-\$202
Skin Biology and Diseases	69,705		64,202		66,783		806'99		66,777		929'99		-101
Muscle Biology and Diseases	75,199		71,527		73,242		73,379		73,235		73,125		-110
Musculoskeletal Biology and Diseases	77,295		74,394		90,877		91,047		90,868		90,732		-136
Bone Biology and Diseases	76,601		83,443		66,210		66,334		66,204	2	66,104		-100
													0
Subtotal, Extramural 43	438,563	5-007	432,895	0.537	432,430		433,240		432,389		431,740		-649
Intramural research 131	50,956	133	51,075	131	50,862	131	50,834	133	51,851	134	52,629	_	778
Res. management & support 81	21,638	78	23,613	84	24,000	84	23,986	84	24,346	85	24,711	,	365
<b>TOTAL</b> 212 5	511,157	211	507,583 215		507,292 215	215	508,060 217	217	508,586 219	219	509,080	2	494

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

### Major Changes in the Fiscal Year 2009 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2009 budget request for NIAMS, which is \$0.4 million more than the FY 2008 budget, for a total of \$509.1 million.

Research Project Grants (-\$0.8 million; total \$331.4 million). NIAMS will support a total of 1,055 Research Project Grant (RPG) awards in FY 2009. Noncompeting RPGs will increase by 4 awards and decrease by \$2.9 million. Competing RPGs will increase by 7 awards and \$2.2 million. The NIH Budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs. NIAMS will continue to support new investigators and to maintain an adequate number of competing RPGs. Intramural Research and Research Management and Support receive modest increases to help offset the costs of pay and other increases.

Research Training (+\$0.139 million; total \$15.6 million). NIAMS will support 319 preand postdoctoral trainees in full-time training positions, the same number as in FY 2008. Stipend levels for NRSA trainees will increase by 1 percent over FY 2008 levels.

Intramural Research (+\$0.8 million; total \$52.6 million). NIAMS will continue to identify areas of potential savings within the Intramural Research Program which will allow us to achieve our program goals and accomplishments. As outlined in the Justification Narrative for the Intramural Research Program area, NIAMS will also pursue new opportunities in clinical and translational science.

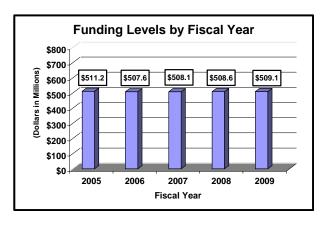
FY 2008 enacted				\$508,586,000
FY 2009 estimated budget authority				509,080,000
Net change				494,000
		2008		
		Enacted	Char	nge from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
Intramural research:				
a. Annualization of January				
2008 pay increase		\$18,810,000		\$210,000
b. January FY 2009 pay increase		18,810,000		408,000
c. One less day of pay		18,810,000		(72,000)
d. Payment for centrally furnished services		9,385,000		141,000
e. Increased cost of laboratory supplies,		00.050.000		454.000
materials, and other expenses		23,656,000		451,000
Subtotal				1,138,000
Research management and support:				
a. Annualization of January				
2008 pay increase		\$10,598,000		\$119,000
b. January FY 2009 pay increase		10,598,000		230,000
c. One less day of pay		10,598,000		(41,000)
d. Payment for centrally furnished services		4,305,000		65,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		9,443,000		188,000
Subtotal				561,000
Subtotal, Built-in				1,699,000

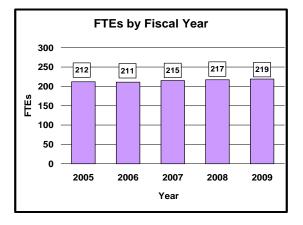
### **Summary of Changes--continued**

		2008		
		Enacted		ige from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research project grants:	=	<b>*</b> 0.40.00 <b>=</b> .000		(40.007.000)
a. Noncompeting	762	\$249,025,000	4	(\$2,927,000)
b. Competing	242	71,130,000	7	2,168,000
c. SBIR/STTR	40	11,979,000	0 11	(29,000)
Total	1,044	332,134,000	11	(788,000)
2. Research centers	38	40,684,000	0	0
3. Other research	176	22,275,000	0	0
4. Research training	319	15,446,000	0	139,000
5. Research and development contracts	57	21,850,000	0	0
Subtotal, extramural				(649,000)
·	<u>FTEs</u>		<u>FTEs</u>	,
6. Intramural research	133	51,851,000	1	(360,000)
7. Research management and support	84	24,346,000	1	(196,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		508,586,000		(1,205,000)
Total changes	217		2	494,000

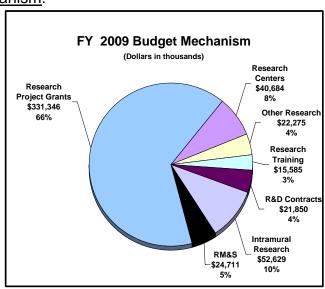
### Fiscal Year 2009 Budget Graphs

### History of Budget Authority and FTEs:

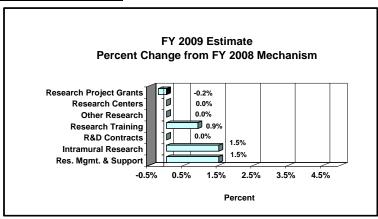




### Distribution by Mechanism:



### Change by Selected Mechanisms:



### Justification of Budget Request National Institute of Arthritis and Musculoskeletal and Skin Diseases

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

### **Budget Authority:**

FY 2	2007	FY 2	2008	FY	2009	Incre	ase or
Actu	ual	Ena	cted	Es	timate	Decre	ase
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	FTEs	<u>BA</u>	<u>FTEs</u>	BA
215 \$50	08,060,000	217 \$50	08.586.000	219 \$50	9.080.000	+2 +\$	3494,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), including NIH/AIDS activities. Details of the FY 2009 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other. The NIAMS is the lead Institute for the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative supported through the NIH Common Fund.

### **DIRECTOR'S OVERVIEW**

### **Institute Mission**

The NIAMS supports a broad range of research, training, and information dissemination activities related to arthritis, musculoskeletal, and skin diseases. Some are rare disorders, but many are very common. All have a major influence on the quality of people's lives. Diseases addressed by NIAMS affect individuals of all ages, of all racial and ethnic backgrounds, and across all economic strata; many disproportionately affect women and minorities.

Over the years, NIAMS-funded research teams have made significant progress on uncovering the causes of many disorders of the bones, muscles, joints, and skin. Most recently, many of these efforts have been possible only because of technological advances, such as those that allow investigators to manage large volumes of data produced by genome-wide association studies or through new imaging technologies.

### **Recent Progress**

In September 2007, the NIAMS released findings from a study of the success of postdoctoral research trainees who received support through the Institute's extramural research training and career development awards program. Like other NIH training and

career development activities, the NIAMS program is intended to help ensure that a diverse and highly trained workforce is available to assume leadership roles related to biomedical and behavioral research. Results of this study were discussed by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council, and the Institute is currently assessing how best to implement recommendations from this report.

A key ingredient in research success is translation of laboratory insights to patient care, and the application of subsequent observations to new laboratory investigations that further improve public health. In this vein, NIAMS launched its Centers of Research Translation (CORT) program and awarded its first round of grants in FY 2006. In FY 2007, the Institute funded a second set of awards, for a total of seven centers addressing conditions such as lupus, orthopaedic trauma, psoriasis, scleroderma, and a genetic form of rickets (a childhood disorder characterized by a softening and weakening of bones). The Centers, which run through FY 2011 or 2012, unite basic and clinical scientists in a way that helps convert research discoveries into new drugs, treatments and diagnostics.

Progress also continues on the Osteoarthritis Initiative (OAI), a large, long-term investment that will expedite the pace of scientific studies and help enable the development of new and improved treatments for patients to preempt disease progression and preserve normal function. Under the leadership of the NIAMS and with support from numerous NIH components and private-sector sponsors, the OAI is creating a publicly available scientific resource to identify and evaluate biomarkers of osteoarthritis for use in clinical research. By the end of FY 2007, more than 600 researchers from 41 countries had registered to access OAI data, and 555 clinical datasets had been downloaded for analysis.

To reach members of underserved populations who are affected by the diseases NIAMS studies, the NIAMS has developed a series of easy-to-read fact sheets on a variety of health topics. Many have been translated into a Spanish-language series called "Esenciales," while others are being published in Chinese. To facilitate dissemination to patients and their health care providers, the NIAMS bundled these materials on a CD-ROM that it is distributing through its Information Clearinghouse, at professional society meetings, and at community health fairs. In FY 2007, the Institute also developed an interactive Web tool, "Check Up On Your Bones," to help people identify the most common red flags that put their bones at risk and give pointers on how to make bones stronger and healthier. Information provided through the tool is relevant for both men and women, and for people of diverse races and ethnicities. The Web tool is an example of personalized medicine allowing the identification of disease risk on an individual, patient-by-patient basis.

### **Future Directions**

Recognizing that the scale and complexity of today's biomedical research problems demand that scientists move beyond their individual disciplines and explore new organizational models for team science, the NIAMS initiated a new research

supplement in FY 2008 to promote interdisciplinary partnerships. The first round of awards will be made for collaborations that bridge specific research topics: autoimmunity and gender/sex factors; autoimmunity or developmental biology and systems biology; soft tissue biology and imaging technologies; and tissue engineering and developmental biology or immunology. Despite having common interests and needs, the fields selected for this pilot program do not have a long history of interactions. However, a modest incentive in the form of a research supplement could stimulate new scientific advances beyond what individual laboratories could attain in the absence of the partnership. If the initial round of supplements generates productive collaborations, the NIAMS may reissue this funding opportunity with a broader scientific scope in the future.

The NIAMS is also pursuing efforts to encourage the use of data from genome-wide association studies (GWAS) that would advance arthritis, musculoskeletal, and skin diseases research. These analytic studies will build on currently-supported projects, including activities being funded through the Genetic Association Information Network (GAIN). Information garnered from such activities could help to predict the potential for disease in a patient before symptoms occur. In addition, the Institute is sponsoring a roundtable discussion on GWAS in the spring of 2008 to develop a better understanding of the various epidemiological resources that are available to the research community, and how the Institute can best leverage these resources and related tools for future studies.

Building on a Memorandum of Understanding that the NIAMS spearheaded in FY 2007 on behalf of the NIH in partnership with the National Aeronautics and Space Administration (NASA), the NIAMS will lead a trans-NIH effort to encourage biomedical researchers to develop projects that could be conducted in the microgravity environment of the International Space Station (ISS). The ISS provides a unique setting where researchers can explore fundamental questions about human health issues, including how the body heals itself, fights infection or develops diseases such as osteoporosis. When the ISS is fully operational in 2011, the U.S. segment will have laboratory space, data processing capabilities, and crew time available for experiments such as those that could be designed by the biomedical research community.

### FY 2009 JUSTIFICATION BY ACTIVITY DETAIL

### **Program Descriptions and Accomplishments**

**Arthritis and Rheumatic Diseases:** The goals of this program are to advance high-quality basic, translational, and clinical biomedical and biopsychosocial research to treat, cure, and prevent arthritis and rheumatic diseases. It utilizes new insights in the fields of genetics, genomics, proteomics, and imaging. The NIAMS is committed to pursuing new opportunities that identify risk factors for these disorders, to enhance disease prediction, and advance prevention strategies.

In FY 2007, the NIH released "The Future Directions of Lupus Research," a scientific planning document that identifies the opportunities, priorities, and needs in lupus research. Future implementation strategies for the plan were discussed at the November 2007 meeting of the Lupus Federal Working Group, which is led by the NIAMS to coordinate Federal efforts in lupus research and education. In addition, the Institute held a scientific roundtable in February 2007 to examine gender and sex factors in inflammation and immune-mediated diseases.

Budget Policy: The 2009 budget estimate for the Arthritis and Rheumatic Diseases program is \$135,103,000, a decrease of \$202,000 or 0.15 percent from the FY 2008 Consolidated Appropriations Act. NIAMS plans for FY 2009 include a continued emphasis on the development and validation of biomarkers related to autoimmune diseases, particularly through participation in a public-private partnership fostering development of systemic lupus erythematosus biomarkers. The Institute will also support studies to further illuminate the role of genetics in various autoimmune disorders. In addition, it anticipates increased focus on innovative therapies for rare rheumatic diseases, such as juvenile idiopathic arthritis, and developing research approaches to better understand chronic musculoskeletal pain in children with arthritis and other diseases. Adaptive clinical trial design will be explored with national thought leaders, to build efficiency in studying interventions in complex, heterogeneous diseases, such as rheumatoid arthritis and systemic lupus erythematosus, and rare diseases.

**Musculoskeletal Biology and Diseases:** The program focuses on understanding the fundamental biology of tissues that constitute the musculoskeletal system, and on translating and applying this knowledge to a variety of diseases and conditions including osteoarthritis. It studies the causes and treatment of acute and chronic injuries -- including carpal tunnel syndrome, repetitive stress injury, and low back pain. The program supports the development of new technologies, such as methods for imaging bone and cartilage to improve the diagnosis and treatment of skeletal disorders, or to facilitate repair of damage caused by trauma to otherwise healthy musculoskeletal tissue.

In FY 2007, the NIAMS formally reorganized its musculoskeletal biology and diseases portfolio to place additional emphasis on musculoskeletal development, tissue engineering, and regenerative medicine (see portrait). Other activities of note included a scientific roundtable to examine opportunities in musculoskeletal injury and trauma, and a session at the Institute's annual scientific planning retreat focused on soft tissue imaging techniques.

<u>Budget Policy:</u> The 2009 budget estimate for the Musculoskeletal Biology and Diseases program is \$90,732,000, a decrease of \$136,000 or 0.15 percent from the FY 2008 Consolidated Appropriations Act. Program plans for FY 2009 include activities building on a scientific discussion of connective tissue biology that the Institute intends to have with members of the research and lay communities later in FY 2008. Basic and translational research on repair mechanisms of tendons, ligaments, and their interfaces with bone and muscle could lead not only to interventions that will stimulate healing

after accidental injury or surgical insult, but also to strategies for engineering functional tissue replacements that could be used when connective tissue is damaged beyond repair. The Program also will continue to lead the Osteoarthritis Initiative (OAI). Developed with support from numerous NIH components and private-sector sponsors, the OAI is building a publicly available scientific resource for identification and evaluation of biomarkers of joint deterioration that can be used in clinical research. All data and resources developed through the OAI are publicly available for scientific investigation; by the end of FY 2007, more than 600 researchers from 41 countries had registered to access OAI data, and 555 clinical datasets had been downloaded.

### Portrait of a Program: Musculoskeletal Development, Tissue Engineering, and Regenerative Medicine

FY 2008 Level: \$23,525,000 FY 2009 Level: \$23,525,000 Change: ---

In FY 2007, the NIAMS formally reorganized portions of its bone biology, cartilage and connective tissue, and orthopaedics portfolios into a new Extramural Research Program for Musculoskeletal Development, Tissue Engineering, and Regenerative Medicine. Since the mid-1980s, researchers have made considerable strides toward developing functional replacement tissues and facilitating tissue regeneration, particularly in the areas of bone, skin, cartilage, and other connective tissues. Through discussions with the Institute's Advisory Council and other leaders in the research community, the NIAMS determined that the musculoskeletal field would further benefit from increased coordination. Because the underlying mechanisms important for the developing organism are likely to be relevant to efforts to grow functional tissue in a laboratory, or to encourage the body to replace damaged or diseased components, the new Program was designed to support research not only in tissue engineering and regenerative medicine, but also in developmental biology.

In addition to overseeing research in these areas, the Program provides a home for NIAMS involvement in trans-NIH bioengineering research efforts -- such as the ongoing program announcement "Enabling Technologies for Tissue Engineering and Regenerative Medicine" and aspects of the NIH Roadmap -- and in the Multi-Agency Tissue Engineering Science Interagency Working Group coordinated by the President's National Science and Technology Council. Because many such advances could be applied to disabling conditions such as osteoarthritis, degenerative disc disease, and sports injuries, the NIAMS expects that research supported under the Program will improve the lives of millions of Americans. Plans for FY 2009 include further integrating developmental biology principles by encouraging new and ongoing efforts by multi-disciplinary research teams.

**Bone Biology and Diseases:** The program covers a broad spectrum of research designed to better understand genetic and cellular mechanisms involved in the build-up and break down of bone. It studies regulation of bone remodeling; bone formation, bone resorption, and mineralization; and effects of hormones, growth factors, and cytokines on bone cells. It supports several large epidemiologic cohorts for characterization of the natural history of osteoporosis, and for identification of genetic and environmental risk factors that contribute to bone disease.

In FY 2007, the NIAMS began a formal evaluation of its bone genetics portfolio to identify resources that, if combined, could provide sufficient statistical power for genome-wide association studies related to bone mass and fracture risk. It also organized three meetings of the Federal Working Group on Bone Diseases, which provides a forum for NIH components and other government agencies to share information on bone-related research.

Budget Policy: The 2009 budget estimate for the Bone Biology and Diseases program is \$66,104,000, a decrease of \$100,000 or 0.15 percent from the FY 2008 Consolidated Appropriations Act. Program plans for FY 2009 include continued support of two epidemiologic studies of fracture risk in women and men—the Study of Osteoporotic Fractures (SOF) and Osteoporotic Fractures in Men study (Mr. OS). In addition to providing valuable information about the medical and demographic characteristics that are associated with low bone mass and potential fracture risk, the long-term studies most recently have linked a popular class of antidepressant drugs (serotonin reuptake inhibitors) with an increased risk of broken bones in older people. They also have made a major contribution to the body of evidence suggesting that anyone over 50 years of age who is being treated for a broken bone should be tested for osteoporosis. Basic and translational research efforts may assess the role of vitamin D in reducing fracture risk. Efforts to address genetic and biochemical factors influencing bone mass and fracture risk in humans also will be implemented upon completion of an evaluation of research resources that could be used by NIH-funded investigators.

**Muscle Biology and Diseases:** The program supports a wide range of basic, translational, and clinical research projects in skeletal muscle biology and diseases. It focuses on fundamental biology of muscle development, physiology, and muscle imaging. Its overarching objective is to advance the understanding of, and, ultimately, prevent and treat the muscular dystrophies, inflammatory myopathies, muscle ion channel diseases, and muscle disorders such as disuse atrophy and age-related loss of muscle mass.

Program activities in FY 2007 included participation in a Request for Applications for the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers and other solicitations to encourage translational research on muscular dystrophies. Staff also convened a small group of researchers for a one-day discussion of how best to evaluate potential therapies for muscle diseases that soon will be ready for clinical testing.

<u>Budget Policy:</u> The 2009 budget estimate for the Muscle Biology and Diseases program is \$73,125,000, a decrease of \$110,000 or 0.15 percent from the FY 2008 Consolidated Appropriations Act. Program plans for FY 2009 include continued funding for the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers awarded in FY 2005 and expected in FY 2008. In addition to these Centers, we will continue to fund basic, translational and clinical research studies of myotonic, Duchenne/Becker, facioscapulohumeral and other muscular dystrophies. Other subjects of interest to the NIAMS that may be pursued through the Muscle Biology and

Diseases program in FY 2009 include non-dystrophic skeletal muscle diseases such as channelopathies, inflammatory and mitochondrial myopathies as well as muscle wasting resulting from disuse or systemic diseases. We will continue our support of studies exploring the causes of muscle diseases and promising treatment strategies such as cell or gene therapy, therapeutic proteins or small molecule drugs.

**Skin Biology and Diseases:** This program supports a broad portfolio of basic, translational, and clinical research in skin, including work on the developmental and molecular biology of skin, the study of skin as an immune organ, and the genetics of skin diseases. The Institute is pursuing opportunities in developing artificial skin, and imaging technologies for diagnosis and tracking progression of skin diseases.

In FY 2007, the NIAMS sponsored a scientific roundtable centered on psoriasis, psoriatic arthritis, and rheumatoid arthritis. Attendees examined the most promising opportunities and critical needs, as seen by the research community. In September 2007, the Institute held a meeting focused on the genetic components of psoriasis to discuss collaborative efforts in identifying the disease's susceptibility genes.

Budget Policy: The 2009 budget estimate for the Skin Biology and Diseases program is \$66,676,000, a decrease of \$101,000 or 0.15 percent from the FY 2008 Consolidated Appropriations Act. NIAMS plans for FY 2009 include continued support for studies focused on the biology and treatment of chronic wounds, to better understand the molecular mechanisms underlying this process with the goal of finding ways to accelerate wound healing and to improve patient outcomes. In addition, the budget estimate anticipates an enhanced emphasis on the genetic factors that contribute to skin diseases such as psoriasis, building on current projects supported by NIAMS and through the Genetic Association Information Network (GAIN). The program will develop additional areas in skin biology to complement its expertise in keratinocyte biology and diseases, and skin immunobiology and immune diseases.

**Intramural Research Program:** The mission of this program is to conduct innovative basic, translational, and clinical research relevant to the health concerns of the Institute, and to provide training for investigators interested in related careers. The program conducts clinical studies on the genetics, etiology, pathogenesis, and treatment of a variety of rheumatic, autoimmune, inflammatory, joint, skin, and muscle diseases.

Over the past year, the program has added clinical staff with expertise in pediatric rheumatology, an area that will continue to be a high priority for the Institute. The program is also benefiting from a new, state-of-the-art gene sequencing system which will support gene expression studies with greater efficiency, lower cost, and increased accuracy than earlier technologies. In addition, this program participates in the new multidisciplinary, trans-NIH Immunology and Inflammation Research Initiative, which will bring together scientists from several NIH institutes who are using common approaches to study multiple disease systems (see portrait).

<u>Budget Policy:</u> The 2009 budget estimate for the Intramural Research Program is \$52,629,000, an increase of \$778,000 or 1.5 percent from the FY 2008 Consolidated

Appropriations Act. NIAMS plans for FY 2009 include an enhanced focus on translational research, in order to facilitate patient-oriented studies in the areas of arthritis, musculoskeletal, and skin diseases, including their genetic, inflammatory, and immune mechanisms. The Institute will enhance its expertise in pediatric rheumatic and musculoskeletal diseases; key recruitments in these areas are currently underway. NIAMS will continue its commitment to multidisciplinary training of rheumatology research fellows, including interactions with other NIH intramural training programs with common scientific interests, to strengthen the pipeline of highly qualified physician-scientists in this field. The Institute's intramural research program anticipates building upon its recent ground-breaking, collaborative studies in 2007, to uncover more information on the genetic underpinnings of chronic, autoimmune, inflammatory diseases.

Portrait of a Program: Clinical and Translational Science in the NIAMS Intramural Research Program

FY 2008 Level: \$16,715,000 FY 2009 Level: \$16,965,000 Change: \$ 250,000

The NIAMS intramural program has pioneered a number of clinical and translational research successes during the Institute's history, including landmark clinical trials that established the efficacy of the arthritis drug anakinra to treat the symptoms and inflammation of the debilitating illness, neonatal-onset multisystem inflammatory disease, or NOMID, and ground-breaking work on the genetic underpinnings of chronic, autoimmune, inflammatory diseases, including rheumatoid arthritis and lupus. The researchers in the intramural program have also made widely-recognized, fundamental discoveries in autoimmunity, which will contribute to the development of new therapies. NIAMS will continue its program in clinical and translational research, to facilitate patient-oriented intramural projects in the NIAMS mission.

In FY 2009, NIAMS will pursue novel research in conditions in which academic health centers have difficulty assembling adequate patient cohorts; innovative clinical trials in disorders lacking effective treatment options; and studies capitalizing on the sophisticated imaging and laboratory technologies available in the NIH Clinical Research Center.

A new director heads the Rheumatology Fellowship Training Program, which fosters interactions among other NIH intramural training programs with common scientific interests. A new pediatric hospitalist enhances the NIH Clinical Center's ability to treat rheumatic disorders in children, and there are ongoing efforts to increase the Institute's expertise in pediatric rheumatology. NIAMS also participates in the new multidisciplinary, trans-NIH Immunology and Inflammation Research Initiative, which will bring together scientists from several NIH institutes who are using common approaches to study a number of diseases. This collaboration will enable the development of clinical research protocols and sharing of resources, such as clinical samples, and a new, state-of-the-art gene sequencing system at NIAMS. This addition to the intramural program will support gene expression studies with greater efficiency, lower cost, and increased accuracy than earlier technologies.

**Research Management and Support (RMS):** NIAMS' RMS supports the scientific, administrative management, and information technology expenses associated with day-to-day operations. It supports long-term investments in the research enterprise, including the review and financial management of applications for grants and contracts,

and dissemination of research results to the American public. In FY 2007, the Institute managed more than 1,261 research grants and centers, as well as 57 research and development contracts and 319 individual and institutional research training grants. NIAMS supports 450 clinical research studies, including 68 clinical trials.

In FY 2007, the NIAMS launched a new public Web site to enhance usability by patients, health care providers, researchers, and the American public. Rigorous reviews by internal and external users were conducted in order to ensure that information was relevant and clearly presented. A unique component of the Web site is a searchable image gallery containing photos and illustrations for use by the public. Items in the gallery are accompanied by abstracts describing each image (see portrait).

<u>Budget Policy:</u> The 2009 budget estimate for RMS is \$24,711,000, an increase of \$365,000 or 1.5 percent from the FY 2008 Consolidated Appropriations Act. NIAMS plans for FY 2009 include activities in support of NIH-wide efforts to enhance the peer review system. The NIAMS will undertake an institute-wide assessment of information technology applications in order to examine functionality and maximize the utilization of available resources. Finally, the Institute will continue to sponsor roundtable discussions and a scientific retreat with extramural investigators and lay representatives to inform the research priority-setting and strategic planning process.

Portrait of a Program: Novel Approaches to Information Dissemination and Health Outreach

FY 2008 Level: \$1,752,000 FY 2009 Level: \$1,778,000 Change: \$ 26,000

The NIAMS is committed to utilizing today's technology to bring the successes of research to all segments of the public. Its redesigned Web site, launched in October 2007, provides a unique, personalized tool for estimating bone health: Check Up on Your Bones (http://www.niams.nih.gov/Health\_Info/Bone/Optool/index.asp). It helps identify the most common red flags that put bones at risk and gives specific strategies to make bones stronger and healthier.

The NIAMS has developed a series of CD-ROMs for health professionals and the public, including Easy-to-Read Health Information on Bones, Muscles, Joints, and Skin in English, Spanish, and Chinese. In addition, the Institute provides an image database (http://images.niams.nih.gov) for researchers, reporters, and the public. The database is composed of photographs of NIAMS scientists, labs, and staff, and seeks to "tell the story" of NIAMS research through pictures.

The NIAMS continues to ensure its research results and health information reach its many special populations. The Institute's Health Partnership Program, particularly through its Community Health Center, addresses health disparities in arthritis and other rheumatic diseases, and provides health education in Washington, D.C., metro area minority communities. NIAMS has also taken a leading role in establishing NIH's American Indian/Alaska Native Health Communications Workgroup, which has sponsored several seminars and other projects. In an effort to broaden outreach to non-English speakers, the Institute has produced selected publications in Spanish and Chinese. As well, a bilingual fotonovela (illustrated storybook) has been developed on osteoporosis and bone health for English/Spanish audiences.

**Budget Authority by Object** 

	uthority by Object		
Tatalana	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Total compensable workyears:	0.47	0.4.0	
Full-time employment	217	219	2
Full-time equivalent of overtime and holiday hours	0	0	0
Average FC colors	¢475.055	¢400.055	¢E 400
Average ES salary	\$175,855	\$180,955	\$5,100
Average GM/GS grade	11.6	11.6	0.0
Average GM/GS salary	\$83,694	\$87,665	\$3,971
Average salary, grade established by act of	φοσ,σσ τ	ψοί, σσσ	φο,στι
July 1, 1944 (42 U.S.C. 207)	\$85,831	\$88,320	\$2,489
		· ·	
Average salary of ungraded positions	111,606	114,843	3,237
	EV 0000	E)/ 0000	1
OD 1507 OL 40050	FY 2008	FY 2009	Increase or
OBJECT CLASSES	Estimate	Estimate	Decrease
Personnel Compensation:	<b>646 007 000</b>	£47.404.000	<b>#004.000</b>
11.1 Full-time permanent	\$16,297,000	\$17,181,000	\$884,000
11.3 Other than full-time permanent	3,508,000	3,694,000	186,000
11.5 Other personnel compensation	493,000	520,000	27,000
11.7 Military personnel	241,000	254,000	13,000
11.8 Special personnel services payments	3,081,000	3,239,000	158,000
Total, Personnel Compensation	23,620,000	24,888,000	1,268,000
12.0 Personnel benefits	5,514,000	5,809,000	295,000
12.2 Military personnel benefits	274,000	290,000	16,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	29,408,000	30,987,000	1,579,000
21.0 Travel and transportation of persons	663,000	646,000	(17,000)
22.0 Transportation of things	143,000	140,000	(3,000)
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	101,000	97,000	(4,000)
23.3 Communications, utilities and			
miscellaneous charges	518,000	505,000	(13,000)
24.0 Printing and reproduction	97,000	94,000	(3,000)
25.1 Consulting services	1,063,000	1,029,000	(34,000)
25.2 Other services	3,864,000	3,765,000	(99,000)
25.3 Purchase of goods and services from			,
government accounts	43,865,000	43,759,000	(106,000)
25.4 Operation and maintenance of facilities	902,000	879,000	(23,000)
25.5 Research and development contracts	15,222,000	15,303,000	81,000
25.6 Medical care	366,000	359,000	(7,000)
25.7 Operation and maintenance of equipment	2,494,000	2,441,000	(53,000)
25.8 Subsistence and support of persons	0	0	) o
25.0 Subtotal, Other Contractual Services	67,776,000	67,535,000	(241,000)
26.0 Supplies and materials	4,858,000	4,754,000	(104,000)
31.0 Equipment	2,359,000	2,308,000	(51,000)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	402,662,000	402,013,000	(649,000)
42.0 Insurance claims and indemnities	0	0	(5.5,500)
43.0 Interest and dividends	1,000	1,000	0
44.0 Refunds	0	0	1 0
Subtotal, Non-Pay Costs	479,178,000	478,093,000	(1,085,000)
Total Budget Authority by Object	508,586,000	509,080,000	494,000

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

### Salaries and Expenses

	•		
OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:	Liladida	Lournato	Booroado
Full-time permanent (11.1)	\$16,297,000	\$17,181,000	\$884,000
Other than full-time permanent (11.3)	3,508,000	3,694,000	186,000
• • • • • • • • • • • • • • • • • • • •	493,000	520,000	27,000
Other personnel compensation (11.5)	,	,	,
Military personnel (11.7)	241,000	254,000	13,000
Special personnel services payments (11.8)	3,081,000	3,239,000	158,000
Total Personnel Compensation (11.9)	23,620,000	24,888,000	1,268,000
Civilian personnel benefits (12.1)	5,514,000	5,809,000	295,000
Military personnel benefits (12.2)	274,000	290,000	16,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	29,408,000	30,987,000	1,579,000
Travel (21.0)	663,000	646,000	(17,000)
Transportation of things (22.0)	143,000	140,000	(3,000)
Rental payments to others (23.2)	101,000	97,000	(4,000)
Communications, utilities and			
miscellaneous charges (23.3)	518,000	505,000	(13,000)
Printing and reproduction (24.0)	97,000	94,000	(3,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	1,063,000	1,029,000	(34,000)
Other services (25.2)	3,864,000	3,765,000	(99,000)
Purchases from government accounts (25.3)	30,425,000	30,322,000	(103,000)
Operation and maintenance of facilities (25.4)	902,000	879,000	(23,000)
Operation and maintenance of equipment (25.	2,494,000	2,441,000	(53,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	38,748,000	38,436,000	(312,000)
Supplies and materials (26.0)	4,855,000	4,751,000	(104,000)
Subtotal, Non-Pay Costs	45,125,000	44,669,000	(456,000)
Total, Administrative Costs	74,533,000	75,656,000	1,123,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

### **Budget Estimate** \$509,080,000 509,080,000 FY 2009 2008 Amount Authorized Indefinite Indefinite 508,586,000 \$508,586,000 FY 2008 Enacted 2007 Amount **Authorizing Legislation** Authorized Indefinite Indefinite U.S. Code Citation 42§241 42§281 Section 402(a) Other Citation Section 301 PHS Act/ Research and Investigation National Institute of Arthritis and Musculoskeletal and Total, Budget Authority Skin Diseases

**Appropriations History** 

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
rear		7 (ilowarioc	Allowarioe	71ppropriation <u>17</u>
2000	309,953,000 <u>2</u> /	333,378,000	350,429,000	351,840,000
Rescission				1,872,000
2001	363,479,000 <u>2</u> /	400,025,000	401,161,000	396,604,000
Rescission				(144,000)
2002	443,565,000	440,144,000	460,202,000	448,865,000
Rescission				(617,000)
2003	485,851,000	485,851,000	489,324,000	489,324,000
Rescission				(3,181,000)
2004	502,778,000	502,778,000	505,000,000	504,300,000
Rescission				(3,234,000)
2005	515,378,000	515,378,000	520,900,000	515,378,000
Rescission				(4,221,000)
2006	513,063,000	513,063,000	525,758,000	513,063,000
Rescission				(5,131,000)
2007	504,533,000	504,533,000	508,583,000	508,240,000
2008	508,082,000	516,044,000	519,810,000	508,586,000
Rescission				(9,043,000)
2009	509,080,000			

<sup>1/</sup> Reflects enacted supplementals, rescissions, and reappropriations.

<sup>2/</sup> Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

### **Details of Full-Time Equivalent Employment (FTEs)**

· · · · · · · · · · · · · · · · · · ·			
OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	52	52	52
Extramural Program	32	32	33
Intramural Research Program	131	133	134
Total	215	217	219
Includes FTEs which are reimbursed from the			
FTEs supported by funds from Cooperative			
Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Avera	age GM/GS (	Grade
2005		11.0	
2005		11.0	
2007		11.6	
2008		11.6	
2009		11.6	

### National Institute of Arthritis and Musculoskeletal and Skin Diseases

### **Detail of Positions**

GRADE         FY 2007 Actual         FY 2008 Enacted         FY 2008 Estimat           Total, ES Positions Total, ES Salary         1 \$167,641         1 \$175,855         \$18           GM/GS-15 GM/GS-14         15 19 19 19 19 6M/GS-13         15 28 29 29 6S-12         29 30 30 30 30 GS-11         22 22 22 22 GS-10         22 22 6S-10         22 6S-10         16 6S-9 15 16 6S-8         16 6S-8 7 7 7 7 6S-7         10 10 10 6S-6 4 4 4 4 6S-5 5 1 1 1 1 1 6S-4 6S-4 6S-3         1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Total, ES Positions         1         1           Total, ES Salary         \$167,641         \$175,855         \$18           GM/GS-15         15         15         15           GM/GS-14         19         19         19           GM/GS-13         28         29         29           GS-12         30         30         30           GS-11         22         22         22           GS-10         0         0         0           GS-9         15         16         16           GS-8         7         7         7           GS-7         10         10         10           GS-6         4         4         4           GS-5         1         1         1           GS-4         0         0         0	1 50,955 15 20 30 30 22 0 16 7 10 4 1
Total, ES Salary         \$167,641         \$175,855         \$18           GM/GS-15         15         15         15           GM/GS-14         19         19         19           GM/GS-13         28         29           GS-12         30         30         30           GS-11         22         22         22           GS-10         0         0         0           GS-9         15         16         16           GS-8         7         7         7           GS-7         10         10         10           GS-6         4         4         4           GS-5         1         1         1           GS-4         0         0         0	15 20 30 30 22 0 16 7 10 4
GM/GS-15       15       15         GM/GS-14       19       19         GM/GS-13       28       29         GS-12       30       30         GS-11       22       22         GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	15 20 30 30 22 0 16 7 10 4
GM/GS-14       19       19         GM/GS-13       28       29         GS-12       30       30         GS-11       22       22         GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	20 30 30 22 0 16 7 10 4 1
GM/GS-13       28       29         GS-12       30       30         GS-11       22       22         GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	30 30 22 0 16 7 10 4 1
GS-12       30       30         GS-11       22       22         GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	30 22 0 16 7 10 4 1
GS-11       22       22         GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	22 0 16 7 10 4 1
GS-10       0       0         GS-9       15       16         GS-8       7       7         GS-7       10       10         GS-6       4       4         GS-5       1       1         GS-4       0       0	0 16 7 10 4 1 0
GS-9 GS-8 7 7 GS-7 10 10 GS-6 4 4 GS-5 1 1 GS-4 1 1 0 0	16 7 10 4 1 0
GS-8 7 7 7 GS-7 10 10 GS-6 4 4 GS-5 1 1 GS-4 0 0	7 10 4 1 0
GS-7 10 10 GS-6 4 4 GS-5 1 1 1 GS-4 0 0	10 4 1 0
GS-6 GS-5 GS-4 4 4 4 1 1 0 0	4 1 0
GS-5 1 1 1 GS-4 0 0	1 0
GS-4 0 0	_
	_
GS-3 0 0	0
GS-2 0 0	0
GS-1 0 0	0
Subtotal         151         153	155
Grades established by Act of	
July 1, 1944 (42 U.S.C. 207):	
Assistant Surgeon General 0 0	0
Director Grade 1 1	1
Senior Grade 0 0	0
Full Grade 0 0	0
Senior Assistant Grade 1 1	1
Assistant Grade 0 0	0
Subtotal 2 2	2
Ungraded 68 68	68
Total permanent positions 177 179	181
Total positions, end of year 233 235	237
Total full-time equivalent (FTE)	
employment, end of year 215 217	219
Average ES salary \$167,641 \$175,855 \$18	0,955
Average GM/GS grade 11.6 11.6	11.6
	7,665

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

### **New Positions Requested**

		FY 2009	
	Grade	Number	Annual Salary
Health Science Administrator	14	1	\$100,876
Research Scientist	13	1	85,367
Total Requested		2	